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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,526	06/27/2003	Ronald J. Link	43738-0003CI (187273)	6041

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EXAMINER	
KOHUT, DAVID M	
ART UNIT	**PAPER NUMBER**
3691	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/607,526	LINK ET AL.	
	Examiner	Art Unit	
	David M. Kohut	3691	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-14 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-14 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 27 June 2003 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 6 October 2003.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Applicant's claim for the benefit of the prior-filed applications 10/299,811, filed 20 November 2002 and 60/332,223, filed 20 November 2001 is acknowledged and accepted.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: "240", "260", and "280". Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "300", "310". Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the

application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. The disclosure is objected to because of the following informalities:

a. Page 2, paragraph 0005, line 13, remove the "s" from "devices";

b. Page 5, paragraph 00016, line16, and page 6, paragraph 00017, line 1, insert character reference "10" after "absolute contraindications";

c. Page 7, paragraph 00021, line 9 and page 8, paragraph 00023, line 6, insert character reference "270" after "customized dynamic informed consent form";

d. Page 9, paragraph 00026, line 9, insert "be" between "would" and "appropriate".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-8, 10, and 12-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Papageorge, U.S. Patent No. 6,584,445, reference A on the attached PTO-892.

8. As per claim 1, Papageorge teaches a computer implemented process for informing a patient of the risk of undergoing a treatment, said method comprising the steps of: (a) gathering semi-static data relating to contraindications to and complications associated with the treatment, i.e. while CHES consults medical experts as well, its outcome projections reflect statistically verified pattern differences in outcomes among treatments using many well-documented, published studies on treatment results to

maximize the accuracy of the information provided and treatment, disease subcategories, concurrent conditions (related or unrelated), patient demographics, and any effect of recent medical advances in each treatment stratify the data from these studies (see column 7, lines 60-67 and column 8, line 1 of Papageorge); (b) gathering dynamic data relating to experienced contraindications to and complications associated with the treatment, said dynamic data comprising information abut the treatment conduct, its result, and patient response over time, i.e. while CHES consults medical experts as well, its outcome projections reflect statistically verified pattern differences in outcomes among treatments using many well-documented, published studies on treatment results to maximize the accuracy of the information provided and treatment, disease subcategories, concurrent conditions (related or unrelated), patient demographics, and any effect of recent medical advances in each treatment stratify the data from these studies (see column 7, lines 60-67 and column 8, line 1 of Papageorge); (c) from the gathered semi-static data and dynamic data, creating a rule-based algorithm for calculating the risks of undergoing the treatment, i.e. these elements are then used to evaluate the costs, risks, and benefits of competing treatments (see column 8, lines 2-4 of Papageorge); (f) acquiring relevant data of an individual patient, i.e. the patient then answers the questionnaire, using single keystrokes to select choices (see column 7, lines 1-2 of Papageorge); (g) calculating a customized personal risk assessment for the individual patient, i.e. the report summarizes the data from the users, with conditional text on how each response affects the course of the disease and the probable results of each treatment option (see column

5, lines 44-47 of Papageorge); (h) presenting the customized personal risk assessment to the patient, i.e. the report summarizes the data from the users, with conditional text on how each response affects the course of the disease and the probable results of each treatment option (see column 5, lines 44-47 of Papageorge).

9. As per claim 2, Papageorge teaches the process of claim 1 as described above. Papageorge further teaches the process wherein the step of creating a rule-based algorithm for calculating the risks of undergoing the treatment comprises: periodically updating both the semi-static data and dynamic data, i.e. CHES will have ongoing system updates to assure that they reflect the latest in medical knowledge and treatment technology to prevent the system from becoming obsolete (see column 9, lines 38-41 of Papageorge).

10. As per claim 3, Papageorge teaches the process of claim 1 as described above. Papageorge further teaches the process wherein the step of creating a rule-based algorithm for calculating the risks of undergoing the treatment comprises: recursively processing the rules governing the risk assessment relating to any treatment based on periodic updates to one or both of the semi-static and dynamic data, i.e. CHES will have ongoing system updates to assure that they reflect the latest in medical knowledge and treatment technology to prevent the system from becoming obsolete (see column 9, lines 38-41 of Papageorge).

11. As per claim 4, Papageorge teaches the process of claim 1 as described above. Papageorge further teaches the process further comprising the step: formulating text material in the form of sentences that list risk factors and outcome information for

display to the patient based on information gathered in the process, i.e. in creating the system conditional text would be written for each possible physician and patient questionnaire response, explaining its positive or negative impact on outcome (see column 9, lines 6-8 of Papageorge).

12. As per claim 5, Papageorge teaches the process of claim 4 as described above. Papageorge further teaches the process further comprising the step: creating a calculus that associates text sentences with the risk information to be presented to the patient, i.e. format a report showing the responses and conditional text, the patient's risk tolerance profile, patient and physician treatment preferences, how they compare to that found to be most cost-effective, and the factors supporting their choice (see column 9, lines 9-13 of Papageorge).

13. As per claim 6, Papageorge teaches the process of claim 1 as described above. Papageorge further teaches the process wherein the step of gathering dynamic data relating to experienced contraindications and complications associated with the treatment includes: identifying a particular treatment provider, and incorporating data relating to the treatment provider, i.e. the users (patient, physician, and insurer) receive outcome data (morbidity and mortality rates) on each treatment and are told that these statistics are compiled from many published studies and must only be used to compare outcomes in their own geographic area (this resembles Prudential Insurance's program of paying patients' travel expenses to centers with the best outcomes on specific procedures) (see column 7, lines 25-32 of Papageorge).

14. As per claim 7, Papageorge teaches the process of claim 6 as described above. Papageorge further teaches the process wherein the step of incorporating data relating to the treatment provider further comprises: gathering and including data on the treatment provider's outcome history associated with the treatment, i.e. the users (patient, physician, and insurer) receive outcome data (morbidity and mortality rates) on each treatment and are told that these statistics are compiled from many published studies and must only be used to compare outcomes in their own geographic area (this resembles Prudential Insurance's program of paying patients' travel expenses to centers with the best outcomes on specific procedures) (see column 7, lines 25-32 of Papageorge).

15. As per claim 8, Papageorge teaches the process of claim 7 as described above. Papageorge further teaches the process wherein the step of incorporating data relating to the treatment provider further comprises: gathering and including data on the treatment provider's complication history in providing the subject treatment, i.e. the users (patient, physician, and insurer) receive outcome data (morbidity and mortality rates) on each treatment and are told that these statistics are compiled from many published studies and must only be used to compare outcomes in their own geographic area (this resembles Prudential Insurance's program of paying patients' travel expenses to centers with the best outcomes on specific procedures) (see column 7, lines 25-32 of Papageorge).

16. As per claim 10, Papageorge teaches a computer-implemented process for informing a patient of the risk of undergoing a treatment, said method comprising the

steps of: (a) gathering semi-static data relating to contraindications to and complications associated with the treatment, i.e. while CHES consults medical experts as well, its outcome projections reflect statistically verified pattern differences in outcomes among treatments using many well-documented, published studies on treatment results to maximize the accuracy of the information provided and treatment, disease subcategories, concurrent conditions (related or unrelated), patient demographics, and any effect of recent medical advances in each treatment stratify the data from these studies (see column 7, lines 60-67 and column 8, line 1 of Papageorge); (b) acquiring relevant data of an individual patient, i.e. the patient then answers the questionnaire, using single keystrokes to select choices (see column 7, lines 1-2 of Papageorge); (c) calculating a customized personal risk assessment for the individual patient, i.e. the report summarizes the data from the users, with conditional text on how each response affects the course of the disease and the probable results of each treatment option (see column 5, lines 44-47 of Papageorge); (d) presenting the customized personal risk assessment to the patient, i.e. the report summarizes the data from the users, with conditional text on how each response affects the course of the disease and the probable results of each treatment option (see column 5, lines 44-47 of Papageorge).

17. As per claim 12, Papageorge teaches the process of claim 10 as described above. Papageorge further teaches the process wherein the step of incorporating data relating to the treatment provider further comprises: gathering performance data relating to a particular treatment provider, including information on treatment outcomes for patients treated by that provider, i.e. the users (patient, physician, and insurer) receive

outcome data (morbidity and mortality rates) on each treatment and are told that these statistics are compiled from many published studies and must only be used to compare outcomes in their own geographic area (this resembles Prudential Insurance's program of paying patients' travel expenses to centers with the best outcomes on specific procedures) (see column 7, lines 25-32 of Papageorge).

18. As per claim 13, Papageorge teaches the process of claim 12 as described above. Papageorge further teaches the process further comprising the step: from the gathered semi-static data, the patient data, and treatment provider data, creating a rule-based algorithm for calculating the risks of undergoing the treatment, i.e. the computer system uses an algorithm for weighing the patient data and the physician data in view of the database (see abstract, lines 9-11 of Papageorge).

19. As per claim 14, Papageorge teaches the process of claim 13 as described above. Papageorge further teaches the process further comprising the step of: recursively processing the rules governing the risk assessment relating to any treatment based on periodic updates to the semi-static data, the patient data, and provider data, i.e. CHES will have ongoing system updates to assure that they reflect the latest in medical knowledge and treatment technology to prevent the system from becoming obsolete (see column 9, lines 38-41 of Papageorge).

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. Claims 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Papageorge, U.S. Patent No. 6,584,445, reference A on the attached PTO-892, in view of Rakshit et al., U.S. Patent No. 5,799,282, reference B on the attached PTO-892.

22. As per claim 9, Papageorge teaches the process of claim 1 as described above. However, Papageorge does not explicitly teach gathering information about pre-operative and post-operative care. Rakshit et al., however, does teach the process which includes gathering information about the pre-operative and post-operative care of the treatment provider's patients, i.e. this interactive process may continue for sections on the alternative choices to an abdominal hysterectomy, post-operative care, pre-operative preparation, etc. (see column 13, lines 57-59 of Rakshit et al.). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the method of Papageorge. One of ordinary skill in the art would have been motivated to incorporate this feature in order to help bridge the gaps that have existed between the legal, medical, consumer and training fields with respect to establishing certifiable informed consent (see column 4, lines 31-34 of Rakshit et al.).

23. As per claim 11, Papageorge teaches the process of claim 1 as described above. Papageorge further teaches printing out the individualized risk assessment, i.e. the report informs physicians and patients of the costs, risks, and benefits of all treatment (see column 10, lines 5 and 8-9 of Papageorge). However, Papageorge does not explicitly teach the process of printing out an informed consent form. Rakshit et al., however, does teach the process comprising printing the individualized risk assessment

as an informed consent form, i.e. upon mastery of all objectives, the system will print an informed consent form, listing the key aspects of the interaction (see column 13, lines 63-64 of Rakshit et al.). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the process of Papageorge. One of ordinary skill in the art would have been motivated to incorporate this feature because using existing techniques, many non-emergency type surgical procedures require the patient to read and sign an "informed consent" form (see column 1, lines 32-34 of Rakshit et al.).

Conclusion

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Kohut, Esq. whose telephone number is 571-270-1369. The examiner can normally be reached on M-Th 730-5 w/1st Fri off. 2nd Fri 730-4.

2. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick J. Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

3. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DMK

12/20/2006

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